N THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Hebert T. Nagasawa et al.

Examiner:

Not yet known

Serial No.:

10/750,005

Group Art Unit:

1646

Filed:

December 30, 2003

Docket No.:

30451.2USU1

Title:

METHODS FOR REDUCING OXIDATIVE STRESS IN A CELL WITH A

SULFHYDRYL PROTECTED GLUTATHIONE PRODRUG

CERTIFICATE UNDER 37 CFR §1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on February 28, 2005.

By: Richelle Ann Domingo

<u>INFORMATION DISCLOSURE STATEMENT</u> (37 C.F.R. § 1.97(b)(3))

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

This statement should be considered because it is submitted before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). In accordance with 37 C.F.R. §1.98(d), copies of Exhibits 20-27 as set forth in the Form 1449 are included herein.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

 Cranskshaw, Duane L. et al., "Double-Prodrugs of L-Cysteine: Differential Protection Against Acetaminophen-Induced Hepatotoxicity in Mice," Journal of Biochemical and Molecular Toxicology, November 5, 2002, 16:235-44. – Exhibit 20 Herbert T. Nagasawa et al. Serial No. 10/750,005 Filed: December 30, 2003

Page 2

- Deneke, Susan M. and Barry L. Fanburg, "Regulation of Cellular Glutathione," American
 Journal of Physiology, October 1989, 257(4):L163-73. Exhibit 21
- Dizdar, Nil et al., "Comparison of N-acetylcysteine and L-2-oxothiazolidine-4-carboxylate as
 Cysteine Deliverers and Glutathione Precursors in Human Malignant Melanoma Transplants
 in Mice," Cancer Chemotherapy and Pharmacology, 2000, 45:192-8. Exhibit 22
- Fernandez-Checa, Jose C. et al., "Mitochondrial Glutathione Depletion in Alcoholic Liver Disease," *Alcohol*, 1993, 10(6):469-75. Exhibit 23
- Holleschau, Ann M. et al., "An HPLC Radiotracer Method for Assessing the Ability of L-Cysteine Prodrugs to Maintain Glutathione Levels in the Cultured Rat Lens," Current Eye Research, May 1996, 15(5):501-10. Exhibit 24
- Meister, Alton, "Glutathione Deficiency Produced by Inhibition of its Synthesis, and its Reversal; Applications in Research and Therapy," *Pharmacology and Therapeutics*, 1991, 51(2):155-94. – Exhibit 25
- Nagasawa, Herbert T. et al., "Protection Against Acetaminophen-Induced Hepatotoxicity by L-CySSME and its N-Acetyl and Ethyl Ester Derivatives," *Journal of Biochemical Toxicology*, November 6, 1996, 11:289-95. – Exhibit 26
- Roberts, Jeanette C. et al., "Prodrugs of L-Cysteine as Protective Agents Against Acetaminophen-Induced Hepatotoxicity.
 (Polyacetoxyalkyl)thiazolidine-4(R)-carboxylic Acids," Journal of Medicinal Chemistry, 1987, 30:1891-6. Exhibit 27

This statement should be considered because it is submitted before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). In accordance with 37 C.F.R. §1.98(a)(2), copies of each document or other information listed on the enclosed Form 1449 are provided.

Herbert T. Nagasawa et al.

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No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102

and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish

that the reference(s) are not "prior art." Moreover, Applicants do not represent that the

references have been thoroughly reviewed or that any relevance of any portion of a reference is

intended.

Consideration of the items listed is respectfully requested. Applicants invite the Patent Office to

request additional information if necessary. Pursuant to the provisions of M.P.E.P. § 609, it is

requested that the Examiner return a copy of the attached Form 1449, marked as being

considered and initialed by the Examiner, to the undersigned with the next official

communication.

No fee is deemed necessary in connection with the filing of this Information Disclosure

Statement. However, if any additional fee is required, authorization is hereby given to charge the

amount of any such fee, or credit any overpayment, to Deposit Account No. 50-0306.

Respectfully submitted,

Sarah B. Adriano

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FORM 1449*	A442 0 c		Docket Number	Application Number
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DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

FORM 1449*

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Docket Number 30451.2USU1 Application Number 10/750,005

Applicant

Herbert T. Nagasawa and Jonathan F. Cohen

Filing Date

Group Art Unit

December 30, 2003

1646

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DATE CONSIDERED

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*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Herbert T. Nagasawa and Jonathan F. Cohen

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CERTIFICATE UNDER 37 CFR 1.8

I hereby certify that this paper or fee is being deposited with the United States Postal as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 28, 2005.

> By: Name: Richelle Ann Domin

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached:

Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.8.

☐ Information Disclosure Statement (37 C.F.R. §1.97 (b)(3))

Form 1449 (Information Disclosure Statement)

Exhibits 20-27

Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

MANDEL & ADRIANO

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